510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k061182

B. Purpose for Submission:
New Device

C. Measurand:
Lipids

D. Type of Test:
Not Applicable.

E. Applicant:
Cliniqa Corporation

F. Proprietary and Established Names:
CLINIQA Liquid QC Lipid Controls Levels 1 and 2
CLINIQA LiniCAL Lipid Calibration Verifiers Levels A - E for Olympus AU Systems
CLINIQA QALIBRATE Lipid Calibrator

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1660 (Quality Control Material)
   21 CFR § 862.1150 (Calibrator)

2. Classification:
   Class I (Quality Control Material)
   Class II (Calibrator)

3. Product code:
   JJY, multi-analyte controls, all kinds (assayed and unassayed)
   JIX, calibrator, multi-analyte mixture

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication(s) for use section below.

2. Indication(s) for use:

   CLINIQA Liquid QC Lipid Controls Levels 1 and 2 are intended for use as assayed quality control material for Apolipoprotein A-1, Apolipoprotein B, Cholesterol (total), High Density Lipoprotein, Low Density Lipoprotein, and Triglyceride analysis.

   CLINIQA LiniCAL Lipid Calibration Verifiers Levels A - E for Olympus AU Systems are assayed, liquid, quality control products which may be used to evaluate the performance of the Olympus AU Systems for Cholesterol (total), High Density Lipoprotein, Low Density Lipoprotein, and Triglyceride at five useful concentrations.

   CLINIQA QALIBRATE - Lipid Calibrator is intended for use in assay method calibration for clinical chemistry analyzers listed in the product insert.

3. Special conditions for use statement(s):

   Prescription Use Only

4. Special instrument requirements:

   The calibration verifiers are to be used with the Olympus AU systems only. The liquid QC controls and lipid calibrator may be used with a number of automated chemistry analyzers which are listed in the product insert.

I. Device Description:

CLINIQA Liquid QC Lipid Controls Levels 1 and 2 are human serum based, containing constituents of human origin, in liquid form, and are ready to use. Preservatives, stabilizers and sodium azide have been added to maintain product integrity.

CLINIQA LiniCAL Lipid Calibration Verifiers Levels A - E for Olympus AU Systems are human serum based, in liquid form, and are ready to use. The product is manufactured without glycol's thereby affording reproducible pipetting characteristics and minimizing undesirable matrix effects. Preservatives, stabilizers and sodium azide have been added to maintain product integrity. Constituent concentrations in Level A are at the low end to allow assessment of the lower limit of the reportable range. Constituent concentrations in Level E are at the high end and are designed to challenge the upper limit of the reportable range. Levels B, C, and D provide intermediate constituent concentrations over the reportable range.

CLINIQA QALIBRATE Lipid Calibrator is human serum based, containing constituents of human origin and purified chemicals and is a liquid calibrator that

does not require reconstitution. Preservatives, stabilizers and sodium azide have been added to maintain product integrity.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   MAS Lipid Control, LiniCAL Chemistry Calibration Verifiers Levels A – E for Olympus AU Systems, Roche Calibrator for Automated Systems.

2. Predicate 510(k) number(s):
   k030679, k033162, and k011658 respectively.

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Lipid Control/Calibrator Verifier/Calibrator	Lipid Control/Calibrator Verifier/Calibrator
Origin	Human serum	Human serum
Analyte	Control: Apolipoprotein A-1, Apolipoprotein B, Cholesterol (total), High Density Lipoprotein, Low Density Lipoprotein, and Triglyceride Calibrator Verifier: Triglyceride Calibrator: High Density Lipoprotein, Low Density Lipoprotein, Triglyceride	Control: Apolipoprotein A-1, Apolipoprotein B, Cholesterol (total), High Density Lipoprotein, Low Density Lipoprotein, and Triglyceride Calibrator Verifier: Triglyceride Calibrator: High Density Lipoprotein, Low Density Lipoprotein
Stability (opened)	Control: 30 days at ºC	Control: 30 days at ºC

Differences		
Item	Device	Predicate
Analyte	Control: Not Present Calibrator Verifier: Cholesterol (total), High Density Lipoprotein, Low Density Lipoprotein	Control: High Density Lipoprotein (precipitate) Phospholipids Calibrator Verifier: Albumin, BUN, Calcium, Creatinine, Lactate, Magnesium, Phosphorus,

Differences		
Item	Device	Predicate
		Total Protein, Glucose, Iron, Sodium, Chloride, Potassium Calibrator: Apolipoprotein A-1, Apolipoprotein B
	Calibrator: Cholesterol (total), Triglyceride	
Stability (opened)	Calibrator Verifier: 30 days at 2-8 ºC Calibrator: 7 days at 2-8 ºC	Calibrator Verifier: 14 days at 2-8 ºC Calibrator: 5 days at 2-8 ºC

K. Standard/Guidance Document Referenced (if applicable):

None were reference.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable.

   b. Linearity/assay reportable range:

   Not applicable.

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Traceability

   The sponsor has not provided any information regarding the traceability of the values assigned to the product. Assays used to establish the assignment of values are performed in at least two laboratories. A minimum of 12 data points are used to determine the mean (expected) value. Within and between assay standard deviations and coefficient of variations (CV) are calculated for each set of data. The Dixon Method for removing outliers from data sets of 3 through 25 observations are used to analyze data sets with CVs greater than 10%. No more than 10% of a set of data are to be removed as a statistical outlier. The resulting data are averaged to obtain a representative expected value for each constituent. All values are assigned with the instrument manufacturer's reagents available at the time of assay.

Stability

Stability characteristics of the CLINIQA Liquid QC Lipid Controls Levels 1 and 2, the CLINIQA LiniCAL Lipid Calibration Verifiers Levels A - E for Olympus AU Systems, and the CLINIQA QALIBRATE Lipid Calibrator were determined using the Arrhenius model of accelerated elevated temperature studies to predict estimated storage stability at 2 - 8 ºC. All samples were tested on the Roche Integra and Olympus AU 400 chemistry analyzers. The data submitted supports an open vial stability of 30 days and an unopened vial stability of 2 years at 2-8 ºC for the Cliniqa Liquid QC Lipid Controls Levels 1 and 2 and the Cliniqa LiniCAL Lipid Calibration Verifiers Levels A - E for Olympus AU Systems. The data submitted supports an open vial stability of 7 days and an unopened vial stability of 1 year at 2-8 ºC for the Cliniqa Qalibrate Lipid Calibrator. Real time stability studies are ongoing.

Expected Values

Expected values are derived from replicate analyses of representative samples of the product and are specific to each lot. Consensus testing data used to establish the expected values were derived from multiple laboratories. A minimum of 12 data points will be used to determine the mean (expected) value. All values are assigned with the instrument manufacturer's reagents available at the time of assay. The values for the specific analyzers are provided in the product insert.

d. Detection limit:
Not applicable.

e. Analytical specificity:
Not applicable.

f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:
Not applicable.

b. Matrix comparison:
Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable.

b. Clinical specificity:

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*
Not applicable.

5. Clinical cut-off:
Not applicable.

6. Expected values/Reference range:
Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.